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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/920,467

Applicant(s)

BLOMQUIST, MICHAEL L.

Examiner

VIVEK D. KOPPIKAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Statement(s) (PTO/SF/42)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Status of the Application

1. Claims 1-5 and 7-19 have been examined in this application. This communication is a Final Office Action in response to the "Amendment" and "Remarks" filed on January 25, 2010.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-20 of copending Application No.09/631.000. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 09/631,000 refers to a database on a computer whereas the instant application refers to a database on a hand-held computer

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and the Office takes the position that a hand-held computer is an obvious form a computer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-6, 16-19 and 16-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed towards a method for creating a library of pump data on a computer having a database but the claims do not positively recite a device (e.g. a computer) which is used for carrying out the method. In these claims, the recited term “database” could be a piece of paper attached to a hand-held computer. Therefore, these claims are not tied to a statutory class of invention. In order to overcome this rejection, the Office recommends amending the claims so that they recite a device (e.g. a computer) which is used in carrying out the claimed method. The applicants are reminded, however, that any amendment(s) to the claim(s) must have support in the specification as it was originally filed.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,788,669 to Peterson in view of US Patent Number 5,713,856 to Eggers and in view of Official Notice view of US Patent Number 6,714,969 to Klein and in even further view of US Patent Number 5,658,250 to Blomquist.

(A) As per claim 1, Petersen discloses a method for creating a library pump data on a computer having a database (Petersen: Abstract), the pump data being organized into sets of program data, each set of program data being available for batch downloading to a medical pump and including data items for controlling operation of the medical pump, the method comprising:

the plurality of data items forming a set of program data (Peterson: Col. 4, Ln. 10-18 and Ln. 36-53);

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical pump entering a plurality of data items into a database on the computer.

However, Eggers discloses data items for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump and controlling operation of the pump based on one or more data items

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(Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson in view of Eggers do not teach that housing is hand held and that it has a form factor, however, this feature is well known in the art as evidenced by Klein (Col. 10, Ln. 41-45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Peterson in view of Eggers with the aforementioned teachings from Klein with the motivation of providing a modular programmable multi-media facility than can be used by portable computing devices or by “portable digital assistants”, as recited Klein (Col. 10, Ln. 41-45).

Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data; however, the examiner takes Official Notice that it was well known in the database arts to assign identifiers to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

The combined teachings of Peterson in view of Eggers in view of Official Notice do not teach or suggest individualized, patient-specific data items, however, this feature

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is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers in view of Official Notice with these aforementioned teachings from Blomquist with the motivation of having a means of allowing a user to download applications into a pump's flash memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).

(B) As per claim 2, Peterson does not explicitly disclose the method of claim 1 wherein the acts of: entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database.

However, Eggers discloses entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database (i.e. drug library (Col. 2, lines 3-10 and col. 11, lines 14-20). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record. However, the Examiner takes official notice that it was well known in the database arts to assign identifiers to data sets and linking data key records to application programs. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of

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Applicant's invention to include assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record within Peterson in view of Eggers in view of Blomquist in view of Klein for the motivation stated above.

(C) As to claim 3, Peterson does not explicitly disclose the method of claim 2 wherein further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump. However, Eggers discloses further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump (Col. 10, Ln. 62 - Col. 11, Ln. 7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and col. 11, Ln. 14-20).

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8. Claims 7-19 are rejected as being unpatentable over Peterson in view of Eggers, in view of Official Notice in view of Blomquist and in view of US Patent Number 6,714,969 to Klein.

(E) As per claim 7, Peterson teaches an apparatus for maintaining a library of program data for medical pumps having a memory, the apparatus comprising: memory loaded with a database, the database including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items (Peterson: Col. 4, Ln. 10-18 and Ln. 36-53). In Peterson the memory is positioned within the housing (Peterson: Figure 1 and Col. 3, Ln. 50-65).

Peterson does not teach that at least some of the program data items included in the database being patient-specific for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; however this feature is well known in the art as evidenced by Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering

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a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson and Eggers do not explicitly disclose a database management system programmed to link a data key to a set of program data; however, the examiner takes Official Notice that it was well known in the database arts to assign identifies to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

Peterson in view of Eggers do not teach that housing is hand held and that it has a form factor, however, this feature is well known in the art as evidenced by Klein (Col. 10, Ln. 41-45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Peterson in view of Eggers with the aforementioned teachings from Klein with the motivation of providing a modular programmable multi-media facility than can be used by portable computing devices or by "portable digital assistants", as recited Klein (Col. 10, Ln. 41-45).

The combined teachings of Peterson in view of Eggers in view of Official Notice do not teach or suggest individualized, patient-specific data items, however, this feature is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers in view of Klein in view of Official

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Notice with these aforementioned teachings from Blomquist with the motivation of having a means of allowing a user to download applications into a pump's flash memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).

(F) As per claim 8, the system of Peterson in view of Eggers in view of Klein in view of Blomquist does not comprise a scanner in data communication with the database management system, the database management system being further programmed to receive a code scanned by the scanner, save the code in a data key record, and link the code to a set of program data, the code being a data key. However the examine takes Official Notice that it was well known in the database art to place a scanner in data communication with the database management system, the database management system being further programmed to receive a code scanned by the scanner, save the code in a data key record, and link the code to a set of program data, the code being a data key. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the above mentioned step within Peterson and Eggers for the motivation stated above.

(G) As per claim 9, the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist further includes a means whereby the medical pump stores a set of program data, the database management system being further programmed to receive the set of program data from the medical pump and save the set of program data as a record in the database (Peterson: Col. 2, Ln. 6-26).

(H) As per claim 10, Peterson teaches an apparatus for batch programming a medical pump, the apparatus comprising: memory loaded with a database (Peterson: Col. 2, Ln. 6-

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25), the database including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items (Col. 2, Ln. 6-24 and Col. 6, Ln. 9-17). a data output configured for data communication with a programmable medical pump(Peterson: Figure 2 and Col. 3, Ln. 66-Col. 4, Ln. 12); and Peterson teaches a processor in electrical communication with the memory and the data output (Peterson: Col. 3, Ln. 66-Col. 4, Ln. 12), the processor configured to retrieve a set of program data from the database and batch download the set of program data to the medical pump (Peterson: Col. 4, Ln. 2-12).

Peterson does not teach that at least some of the program data items included in the database being patient-specific data items for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; however, Eggers discloses data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the

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motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data; however, the examiner takes Official Notice that it was well known in the database arts to assign identifiers to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

Peterson in view of Eggers do not teach that housing is hand held and that it has a form factor, however, this feature is well known in the art as evidenced by Klein (Col. 10, Ln. 41-45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Peterson in view of Eggers with the aforementioned teachings from Klein with the motivation of providing a modular programmable multi-media facility than can be used by portable computing devices or by “portable digital assistants”, as recited Klein (Col. 10, Ln. 41-45).

The combined teachings of Peterson in view of Eggers in view of Official Notice do not teach or suggest individualized, patient-specific data items, however, this feature is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers in view of Official Notice with these aforementioned teachings from Blomquist with the motivation of having a means of

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allowing a user to download applications into a pump's flash memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).

(I) As per claim 11, the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist comprises a serial communication cable connected to the data output (Peterson: Col. 3, Ln. 65-Col. 4, Ln. 12).

(J) As per claim 12, the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist further comprises a medical pump in data communication with the data output (Peterson: Col. 3, Ln. 65-Col. 4, Ln. 12).

(J) As per claim 13, the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist teaches each data key record includes first and second fields, the first field for storing an identification code and the second field from storing a name in prose (Eggers: Col. 10, Ln. 62 - Col. 11, Ln. 7). The motivation for making this modification to Peterson is the same as that set forth, above, in the rejection of Claim 10.

(K) As per claim 14, in the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist each data key record includes fields for a patient I.D., a therapy I.D., and a fluid I.D (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7). The motivation for making this modification to Peterson is the same as that set forth, above, in the rejection of Claim 10.

(L) As per claim 15, in the apparatus of Peterson in view of Eggers in view of Klein in view of Official Notice in view of Blomquist the processor is programmed to generate a user interface, the user interface including a plurality of graphical fields for program

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data (Eggers: Figure 21 and Col. 16, Ln. 39-45). The motivation for making this modification to Peterson is the same as that set forth, above, in the rejection of Claim 10.

(M) As per claim 16, Peterson teaches a method for batch programming a medical pump (Peterson: Abstract), the method comprising: selecting a set of program data (Peterson: Col. 2, Ln. 4-26) and batch downloading the set of program data to the medical pump, wherein the set of program data is downloaded to the medical pump without intervening action by a user after the first data item is downloaded to the computer (Col. 5, Ln. 31-44). Peterson does not teach that a set of program data including data items for controlling operation of a medical pump.

However, Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). Eggers also teaches the following: batch-downloading the plurality of data items into the memory within the pump and controlling operation of the pump based on one or more data items (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the

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motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson in view of Eggers do not teach or suggest that the apparatus that downloads data to the pump is hand-held, however, examiner takes the position that this feature is well known in the art as evidenced by Klein (Col. 1, Ln. 66-Col. 2, Ln. 7). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the teachings of Peterson in view of Eggers with the motivation of having a means to transmit data to peripheral devices, as recited in Klein (Col. 2, Ln. 3-7).

The combined teachings of Peterson in view of Eggers in view of Official Notice do not teach or suggest individualized, patient-specific data items, however, this feature is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers in view of Official Notice with these aforementioned teachings from Blomquist with the motivation of having a means of allowing a user to download applications into a pump's flash memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).

(N) As per claim 17, the method of Peterson in view of Eggers in view of Official Notice in view of Klein in view of Blomquist teaches an information management system is loaded on a computer and the information management system includes a database storing a plurality of data keys and a plurality of program data sets, and wherein the act of selecting a set of program data comprises: entering a data key into the information management system; referencing the data key to a program data set; and retrieving the referenced program data set from the database (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45).

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The motivation for making this modification to Peterson is the same as that set forth, above, in the rejection of Claim 16.

(O) As per claim 19, the method of Peterson in view of Eggers in view of Official Notice in view of Klein in view of Blomquist teaches an information management system is loaded on a computer and the information management system includes a database storing a plurality of data keys and a plurality of program data sets and the act of batch downloading the set of program data includes downloading the set of program data from the computer to the medical pump, the method further comprising: uploading the set of program data from the medical pump to the computer after it is downloaded to the medical pump (Eggers: Col. 5, Ln. 6-17 and Ln. 46-54)); comparing the set of program data that was download to the medical pump to the set of program data that was uploaded from the medical pump (Eggers: Col. 5, Ln. 6-17); and generating an error if the set of program data that was downloaded from the medical pump is not identical to the program data that was uploaded from the medical pump (Eggers: Col. 5, Ln. 14-17). The motivation for making this modification to Peterson is the same as that set forth, above, in the rejection of Claim 10.

9. Claim 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view Eggers in view of Blomquist in view of Official Notice in view of Klein in view of Blomquist as applied to claim 3 above, and in further in view of “Acute Health Solutions”

(A) As to claim 4, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer,

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wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data.

However, “Acute Health Solutions” discloses wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data (see abstract and page 2, paragraph 3). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data as disclosed by “Acute Health Solutions” within the Peterson system for the motivation of insure association of the drug and concentration with a pump rate and an infusion amount (Abstract).

(B) As per claim 5, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump. However, “Acute Health Solutions” discloses wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump (see abstract and page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of

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program data items from the pump as disclosed by “Acute Health Solutions” within the Peterson system for the motivation of insure association of the drug and concentration with a pump rate and an infusion amount (Abstract).

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of Eggers in view of Official Notice and in view of Klein in view of Blomquist as applied to claim 17 above, and in further in view of “Acute Health Solutions”

(A) As per claim 18, the method of Peterson in view of Eggers does not disclose that the act of entering a day key includes scanning a bar code, however, this feature is well known in the art as evidenced by Acute Health Solutions (Abstract and Page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump as disclosed by “Acute Health Solutions” within the Peterson system for the motivation of insure association of the drug and concentration with a pump rate and an infusion amount (Acute Health Solutions: Abstract),

Response to Arguments

11. Applicant's arguments filed January 25, 2010 have been fully considered but they are not persuasive. Applicants arguments will be addressed in sequential order as they were presented in the “Remarks” section filed on January 25, 2010.

(1) Applicants argue that the 35 U.S.C. 101 has been overcome because the claims recite the use of a hand-held computer. However, the Office would like to point out that this rejection has not been overcome because even though a hand-held computer

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is recited in the claims it is still possible that the method delineated in the claims could be performed by a human with the computer or device being a passive component of the claimed method. Therefore, even though the claims recite a device or machine in the method the Office believes that the steps of the claims are not adequately tied to this device or machine. To overcome this 35 U.S.C. 101 rejection the Office recommends amending the claims so that the device or machine claimed in the steps is actively performing one or more of the steps in the claimed method.

(2) The applicants argue that the Office does not include any analysis or discussion about why it would have been obvious to modify the other cited references in view of Blomquist to batch download individualized, patient-specific data. However, the Office does in fact provide the following motivation statement as being a reason that would motivate one of ordinary skill in the art to modify the cited references with the teachings from Blomquist:

“The combined teachings of Peterson in view of Eggers in view of Official Notice do not teach or suggest individualized, patient-specific data items; however, this feature is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of Peterson in view of Eggers in view of Official Notice with these aforementioned teachings from Blomquist with the motivation of having a means of allowing a user to download applications into a pump's flash memory without having to enter the information through a keyboard, as recited in Blomquist (Col. 12, Ln. 4-11).”

(3) Applicants argue that the Eggers and the Blomquist reference teach away from a claimed combination of batch downloading and individualized, patient-specific

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data items. However, the Office would like to point out that the Blomquist reference clearly states the limitation of downloading individualized, patient-specific data items (Blomquist: Col. 11, Ln. 64-Col. 12, Ln. 10). This cited portion of Blomquist teaches batch downloading individualized, patient specific parameters and it states that one of the advantages of doing so is so that numerous, patient-specific inputs would not have to be individually entered or entered using the keyboard.

Applicants also state that in Col. 10, lines 15-17 of Blomquist there is a discussion of using prompts for entering a “particular setting.” However, the Office would like to point out that despite this disclosure in Blomquist, the Blomquist reference goes on to disclose that individualized, patient-specific can be batch-downloaded into a memory (Blomquist: Col. 11, Ln. 64-Col. 12, Ln. 10).

As a further note the Office would like to point out that Applicants make the following statement in their response (Page 3, 1st Full Paragraph) “[a]lthough the claims may not be so limited, Blomquist also does not teach that any patient specific data is batch downloaded.” Therefore it seems that the applicants are admitting that the claims of the Blomquist reference disclose the embodiment of batch downloading individualized, patient-specific data.

The Office would further like to point out that batch downloading is also mentioned in Figure 4 B (Item 150) Col. 12, Ln. 10-35 of Blomquist. This recited section of Blomquist discusses performing a status check each time there is an application download to the flash memory of the pump. Downloading various applications to the flash memories of pump implies and includes batch downloading patient specific data.

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(4) Applicants argue that the Eggers reference explicitly distinguished between loading libraries and data such as RATE and VTBI into a pump and that in Eggers a drug library is loaded in a pump with a PCMIA interface or similar data communication interface, while settings such as RATE and VTBI are entered directly and individually into the pump as discussed above. The applicants then go on to argue that both references teach individually entering data such as RATE, not batch-downloading such data items.

To respond to this argument the Office would like to point out that the Blomquist reference is relied on to show that the feature of batch-downloading individualized, patient-specific data is known in the prior art and the Eggers reference is not relied upon for this purpose.

Applicants also argue that both Eggers and Blomquist teach individually entering such data such as RATE, not batch-downloading such data items. However, the Office would like to point out that the claims do not explicitly claim the step of batch-downloading RATE. The claims implicitly recite the step of "batch-downloading individualized, patient-specific data items" and as noted above this step is taught in Blomquist (Col. 11, Ln. 64-Col. 12, Ln. 10).

(5) With regards to the applicants statement regarding the double-patenting rejection over the claims, the Office would like to point out that this rejection still stands and that the applicants may file a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) and this terminal disclaimer may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this

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application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be

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obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Primary Examiner, Art Unit 3686

8/24/2010